K091230

510(k) Summary

Submitter: Photon Technologies Corporation
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Summary prepared: April 20, 2009

AUG 12 2009

Device Name
Trade/Proprietary name: HDR Prostate Template and Accessories
Common or Usual name: Applicator for Remote Controlled Afterloading Brachytherapy
Classification name: System, Applicator, Radionuclide, Remote-controlled
21 CFR 892.5700, Class II, Product Code JAQ

Predicate Device: Nucletron Corporation, Prostate Stepper Template Set, K003270

Description
The Photon Technologies HDR Prostate Template and Accessories are designed to work as accessories to commercially available high dose rate remote afterloader systems and consists of a template, plastic needles and needle obturators.

The template is designed to mount on various ultrasound stepping devices and the grid of needle sized holes is compatible with the standard ultrasound image grid. The template is also designed with a simple locking mechanism for holding the needles in place and suture holes for suturing the template to the patient.

The needle is a plastic tube that is closed to a sharp point at one end and equipped with a metal connector for attaching the needle to the remote afterloader transfer tube on the open end.

The needle obturator is a spring temper metal rod that is inserted into the needle before use to straighten and stiffen it before implantation and to prevent damage between treatments or the possible entry of bodily fluids or other foreign matter.

The HDR Prostate Template and Accessories are single use accessories that are provided unsterile and whose components are compatible with steam autoclave sterilization.

Intended Use
The Photon Technologies HDR Prostate Template and Accessories are intended to be used as accessories to commercially available high dose rate remote afterloader systems for prostate brachytherapy. The template allows the precision alignment, placement, and position retention of the HDR needles. The HDR needles and

associated obturators provide a treatment path to the prescribed area for the radiation source while preventing the source from coming into contact with bodily fluids.

Summary of Technological Characteristics

This new device is substantially equivalent to the predicate device in design, construction, and function. A comparison summary of technological characteristics between the new device and the predicate device is listed in section 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeffrey A. Edwards
President
Photon Technologies Corporation
1572 Hwy. 85 N, Ste 308
FAYETTEVILLE GA 30214

AUG 12 2009

Re: K091230
Trade/Device Name: HDR Prostate Template and Accessories
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: July 14, 2009
Received: July 14, 2009

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091230

Device Name: HDR Prostate Template and Accessories

Indications For Use:

The HDR ProstateTemplate and Accessories are indicated for use as an accessory to commercially available high dose rate remote afterloading systems for prostate brachytherapy.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091230